

Rula Ibrahim-Saker, Pharm.D.
Director, Regulatory Strategy

Dr. Rula Ibrahim-Saker is a Director of Regulatory Strategy at Advyzom. She provides strategic and tactical regulatory services across all phases of drug development and therapeutic areas for Advyzom clients. Rula has led successful IND submissions, prepared Fast Track, Qualified Infectious Disease Product (QIDP) Designation requests. She also leads the development of FDA Briefing Packages for key milestone meetings, labeling, regulatory strategic plans, and risk assessments. Rula has diverse experience across therapeutic areas including anti-infectives, dermatology, ophthalmology and virology. She understands the complex US regulatory environment and is skilled at providing research and regulatory precedent in different therapeutic areas. Rula brings strong expertise to clients through her role as a US agent and as a liaison to the FDA.

Rula has over ten years of drug regulatory affairs experience in the pharmaceutical industry. Prior to joining Advyzom, Rula was a Regulatory Lead for marketed products at Hoffman La Roche where she was an FDA liaison. In this capacity, she was involved in Regulatory Strategy, managing programs from a regulatory perspective, leading REMS activities, and preparing teams for advisory committee meetings. Rula participated in FDA meetings and prepared teams for these interactions, including development of briefing packages.

Prior to Roche, Rula was in a Pharm.D. Post Doctoral fellowship program concentrated on clinical development and regulatory affairs for Phase I-III drug development. She prepared IND annual reports and updated investigator brochures, created briefing packages and developed competitive intelligence assessments for various diseases. Early in her career, Rula had worked as a Pharmacy Intern at Bristol Myers Squibb Company, as well as a Lab Director at St. Louis Hospital in Damascus, Syria.

Rula earned her Doctor of Pharmacy degree from Rutgers University. She received her Master's Degree with honors in Laboratory Diagnosis at The University of Damascus School of Pharmacy, and a Bachelor Degree in Pharmacy & Pharmaceutical Chemistry at the University of Damascus, Syria. She is a Registered Pharmacist.